

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body” in Regard to Orthotic and Prosthetic Devices Regulation 1591, *Medicines and Medical Devices*

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be amended to clarify the definition of “worn on the body?”

II. Staff Recommendation

Staff recommends that the regulation be amended as illustrated in Exhibit 1, including:

- Amend subdivision (a)(4) to include surgical clinics in the definition of health facility as published in the Board’s December 20, 2001 Memorandum Opinion in the Matter of the Bergen Brunswick Drug Company, and as provided in AB 646 (2001).
- Add subdivision (e)(8) to provide that sales of continuous passive motion devices are exempt from tax, as published in the Board’s April 18, 2002 Memorandum Opinion in the Matter of Action Medical Products, Inc.
- Move the reference to bags and tubing, filters, locks, tape, etc., used to dispense enteral feeding, TPN or IDPN to the patient from subdivision (b)(5) to new subdivision (e)(9).
- Correct cross-references in subdivisions (c)(1) and (e)(7) to read “subdivision (b)(5)” and “Regulation 1591.1(b)(5)” respectively.

III. Other Alternatives Considered

As proposed by Mr. Glenn Bystrom and Ms. Suzanne Beaudelaire of Ernst & Young LLP (E&Y), revise subdivisions (b)(4) and (b)(5) of the regulation. E&Y’s proposed revisions are illustrated in Exhibit 2 and provide that, if the price paid for the orthotic or prosthetic device is predominantly for the part that is worn on the body, the device is a medicine and its sale is exempt from tax. If the price paid for the device is predominantly for the part that is not worn, then only the price attributable to the part that is worn may be excluded from tax.

As proposed by Ms. Jacqueline Reynolds of Action Medical Products, Inc. on January 14, 2002, eliminate the requirement that a device be wholly worn on the body.

In her letter dated May 6, 2002, Ms. Janet Smith of Smith Bio-Medical (Smith) proposes to include all wound dressings in the definition of “medicines,” the sales of which are exempt from tax.

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

IV. Background

Surgical Clinics – Subdivision (a)(4)

Assembly Bill 646 (Horton), Chapter 706 (2001), amended Revenue and Taxation Code (RTC) section 6369 to incorporate a cross-reference to section 1200 of the Health and Safety Code. This law change, operative April 1, 2002, expands the definition of “health facilities” to include surgical clinics and similar outpatient health facilities for the treatment of human beings, and resulted in sales of medicines to surgical centers receiving the same exemption as was previously available to hospitals.

In addition, on December 20, 2001, the Board published its Memorandum Opinion in the Matter of Bergen Brunswick Drug Company and concluded that sales of prescription medicines to surgery centers qualify as exempt sales of medicines, even though the surgery centers were not health facilities as defined under Health and Safety Code section 1250. The Memorandum Opinion is retroactive past the operative date of the statute.

“Worn on the Body,” Dressings

History

Sales of medicines were subject to tax until January 1, 1962, when a specific exemption was enacted for sales of prescription medicines. Over the years, a number of bills have been enacted to extend this exemption to other related commodities or articles. In 1977, the Legislature extended the exemption to include sales of various prosthetic and orthotic devices. Regulation 1591, which was adopted in 1962, was amended accordingly to exempt sales of orthotic and prosthetic devices that meet defined conditions, including the requirement that these devices be designed to be worn on the body of the user. The regulation was further amended in 1978 and 1999 to add specific examples of orthotic and prosthetic devices that are included or excluded from the term “medicines.” Effective March 2000, the Board incorporated its long-standing interpretation and further clarified precisely what is meant by the language “worn on the body,” stating that “if any part of the orthotic device is not worn on the person, the device is not a medicine for purposes of this regulation.” The regulation was also amended in December 2000 to clarify that specified devices used to administer liquid nutrition are included in the term “prosthetic devices.” Articles that are in the nature of compresses and dressings have been excluded from the definition of medicines in the statute and in the regulation since 1963.

Current Application of Tax

Under current law, sales of devices or appliances, and articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

equipment or article are subject to tax since the statute specifically excludes these items from the definition of “medicines.” (RTCSection 6369(b)(2).) Accordingly, sales of wound dressings are generally subject to tax. However, the Legislature has included within the definition of “medicines” certain named devices, instruments, apparatus, appliances, and physical equipment. Among other things, RTC section 6369(c) provides that the following devices are included in the definition of “medicines” under defined conditions. As noted in the following subsections, one of these conditions is that they be worn on the body of the user (emphasis added):

(c)(3)(A) - Orthotic **devices**, other than orthodontic devices, **designed to be worn on the person of the user as a brace, support, or correction for the body structure**, and replacement parts for these devices...

(c)(4) - Prosthetic **devices**, and replacement parts for those devices, **designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body**...

In addition to the foregoing limitation on their exempt sales, orthotic and prosthetic devices must be generally sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6) of Regulation 1591. (See Exhibit 1).

Action Medical Products, Inc. Memorandum Opinion – Exhibit 3.

The Board’s April 18, 2002 Memorandum Opinion in the Matter of Action Medical Products, Inc. found that the petitioner’s continuous passive motion (CPM) machines that are not fully worn on the body serve the identical medical rehabilitation purposes as those that are fully worn on the body. The Board concluded that the CPM machines at issue in this case qualify as orthotic devices pursuant to section 6369, subdivision (c)(3)(A), even though they were not fully worn on the body.

Continuous Passive Motion Devices

The Center for Orthopedics and Sports Medicine defines continuous passive motion as follows:

...a postoperative treatment method that is designed to aid recovery after joint surgery. In most patients after extensive joint surgery, attempts at joint motion cause pain and as a result, the patient fails to move the joint. This allows the tissue around the joint to become stiff and for scar tissue to form resulting in a joint which has limited range of motion and often may take months of physical therapy to recover. Passive range of motion means that the joint is moved without the patient's muscles being used. Continuous Passive Motion devices are machines that have been developed for patients to use after surgery.

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

An interested parties meeting was held on January 3, 2002, to discuss Industry concerns regarding the current application of tax to orthotic and prosthetic devices. As a result of the meeting, staff received comments from interested parties regarding the definition of “worn in or on the body.” This topic was placed on the Business Taxes Committee’s April 17, 2002 agenda and subsequently removed. It has recently been rescheduled for discussion at the July 31, 2002 Business Taxes Committee meeting.

V. Discussion

Surgical Clinics

Staff proposes to add a reference to Health and Safety Code section 1200 in Regulation 1591(a)(4) in order to include surgical clinics in the definition of “health facilities” without the operative date contained in the statute. This will conform the regulation to the Board’s April 18, 2002 Memorandum Opinion.

“Worn on the Body”

Staff Recommendation

Staff proposes to include CPM machines, if fully worn on the body or functionally equivalent to those fully worn on the body, in the list of Specific Applications in Regulation 1591(e), making sales of these devices exempt from tax. This will conform the regulation to the Board’s April 18, 2002 Memorandum Opinion. Sales of devices that are not specifically listed as exempt in the regulation remain subject to tax.

E&Y and Reynolds Proposals

E&Y’s proposed revisions (see exhibit 2) would interpret the statutory phrase “designed to be worn on or in the body of the user” to mean that if the price paid for the device is predominantly for the part that is worn, the sale of the device is exempt from tax. If the price paid for the device is predominantly for the part that is not worn, then only the price attributable to the part that is worn may be excluded from tax. E&Y believes these revisions represent a reasonable compromise between “worn” and “fully worn.”

E&Y disagrees with the current provision in subdivision (b)(4) of the regulation, which provides that if any part of the orthotic device is not worn on the person, the device is not a medicine for the purpose of Regulation 1591. While the statute states that the device must be designed to be worn on the body, it does not state that the device must be “fully” worn and, in E&Y’s view, a device can be designed to be worn and not be fully worn. In addition, since the Board amended subdivision (b)(5) in 2000 to include tubes, connectors, needles, bags and syringes used to dispense enteral feeding to the patient in the definition of prosthetic devices, E&Y argues that drainage bags that are bed or pole-mounted and

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

attached to the patient through a series of tubes and connectors should equally be included in the exemption provided for sales of prosthetic devices. For the same reason, sales of I.V. tubes, connectors, syringes and bags used for administration of medication and hydration fluids should be exempt from tax since, in E&Y’s view, this method replaces the functioning of body parts that ordinarily allow for oral intake of medications and fluids.

Ms. Reynolds believes that the requirement that devices be wholly worn on the body should be eliminated since the regulation requires that devices replace the function of a natural part of the human body. She argues that a device may replace the function of the human body without being wholly worn. Ms. Reynolds believes the “wholly worn” requirement is overshadowed by the device’s ability to “replace a function of the human body” and should be removed from the regulation.

Staff’s Response to E&Y and Reynolds Proposals

RTC section 6369 has two components: (1) the items must be “devices” and (2) the devices must be “worn on the person” of the patient. Both of these elements must be given effect. In administering the statutory phrase “devices ... worn on the person of the user,” a line must be drawn between devices that are worn on the person of the user and those that are not. Staff believes the logical place to draw that line is that the entire device must be worn on the person of the user, which has been the Board’s long-standing interpretation of the statute. The words in the statute must be interpreted according to their plain meaning. In addition, all of the words of the statute must be interpreted together to determine the intent of the Legislature in granting the exemption. In order to perform their function, all prosthetic and orthotic devices must be attached to the body in some way. Therefore, it is logical to assume that the phrase “worn on the body” is intended to limit the exemption. The statute uses the word “devices,” and not “part of the devices.” While the term “device” is not defined in the Revenue and Taxation Code, it is defined in the Health and Safety Code. Health and Safety Code Section 109920(b) defines “device” as meaning “any instrument, apparatus, implement, machine, contrivance, ... or other similar or related article, including any component, part or accessory that is ... [i]ntended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment or prevention of disease in humans or any other animal.” (Emphasis added.) This definition has been in the Code since 1939 and is the definition on which RTC section 6369(b)(2) is based. “Worn” is defined as “to be fitted with or have on the person habitually.” (Wm. Morris, ed., The American Heritage Dictionary. New York: American Heritage Publishing Co. 1975.) Based on the language of both statutes, the Board’s interpretation since 1977 has been that mere attachment to the body is not enough to qualify for the statutory exemption, whether or not the component that is attached to the body has more value or is larger than the component that is not.

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

Staff has several concerns with E&Y’s proposal to replace the current requirement that orthotic and prosthetic devices be fully worn on the body with a test based on the predominant value of the part that is worn on the body of the user. First, it is the medical industry’s established practice to sell orthotic and prosthetic devices as units and bill the units on a lump-sum basis. Therefore, attempting to determine the portion of the selling price that represents the component part of the unit that is “worn” on the body would be difficult and subjective. If the taxpayer does not provide a breakdown, the entire cost of the device would remain taxable under current case law. Any attempt on the part of the auditor to make an apportionment would of necessity be costly and time consuming for both the State and taxpayers. In addition, the auditor may have to rely on factors that apply to retailers other than the one under audit, which could be seen as being arbitrary.

The second concern is that, as explained above, in enacting the specific exemption, the Legislature stated that the “devices,” not component parts of the devices, must be designed to be worn in or on the body of the user. (The Legislature did grant the exemption to sales of “replacement parts” but not to initial sales of “parts” of the devices.) In other words, the sale of the entire device is or is not exempt from tax in the statute. When a “device” is an interconnected system of parts all of which must be present and working for the device to operate, the entire system must be worn on the body of the patient for the exemption to apply. (See Health & Safty Code Section 109920.) In addition, since the statute also exempts sales of “replacement parts for these devices,” staff has consistently treated separate sales of replacement parts as exempt when the device is fully worn on the body. E&Y’s proposal parses the word “worn” out from the rest of the statute and places its focus on that word alone. As an administrative agency, the Board must, as discussed above, give effect to all of the words of the statute, not just a carefully chosen few. Under E&Y’s proposal the question becomes, what component of a replacement part that has one end attached to the human body and the other to a motor or pump would be subject to tax?

Another concern is that the use of term “predominantly” is too general to be applied on a consistent basis. Does “predominantly” mean more than 50 percent, 80, 90 or 95 percent? The Office of Administrative Law may reject such a standard on the grounds that it violates the “Clarity” standard in the Administrative Procedure Act. (Govt. Code Section 11349.1(a).)

E&Y also suggests that Annotations 425.0269.800, 425.0492.500, 425.0884.5 and 425.0391 be deleted due to what they believe to be “[an] unsupported general restriction that has been placed on what qualifies as exempt orthotics or prosthetics.” E&Y contends that these annotations “restrict exempt orthotic [and prosthetic] devices to those that allow patients to be ambulatory,” and “there is no mobility requirement in the regulation, and it is not supported by the language in the statute.”

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body”

Regulation 1591, *Medicines and Medical Devices*

Staff agrees that the statute does not require the patient to be ambulatory, and believes that such requirement has not been used as a basis for denying a prosthetic or orthotic exemption in the past. Staff believes that the references in the annotations to patient mobility are derived from the factual circumstances underlying the subject annotations, but will review them as part of the implementation process for any amendments approved for Regulation 1591. To the extent that these annotations are found to conflict with the regulation, they will be deleted or revised for clarity.

Smith Proposal

Smith believes that sales of wound care dressings should be exempt from tax because they are worn directly on the open flesh of the body. In addition, Smith states that, “in order to meet Federal, State and IIMO requirements for reimbursement, all dressings must be prescribed, just like medicines.”

Staff’s Response to Smith Proposal

Dressings are specifically excluded from the term “medicines” in both the statute and the regulation. Dressings are not “devices.” Specifically, they are not considered to be orthotic devices that are worn on the body as a brace or support to correct the body structure, or prosthetic devices that assist or replace the functioning of a natural part of the human body. As such, their sales are generally subject to tax.

Enteral Feeding

I.V. sets, bags, tubes, filters, connectors, clamps, syringes, etc. are instruments and appliances that are specifically excluded from the term “medicines” in the statute and in the regulation. In December 2001, the California Superior Court ruled in favor of the Board in the matter of *Eisenhower Medical Center, et al. v. State Board of Equalization*, (*San Francisco County Superior Ct. No. 994945 (12/10/2001)*) upholding the Board’s position that I.V. sets and reagents are not medicines for purposes of Regulation 1591 and their sales are subject to tax. The only items excluded from that decision were sets related to enteral, IDPN and TPN feeding, which the Board conceded based on amendments to Regulation 1591 in December 2000. In these amendments, the Board concluded that TPN, IDPN, and food provided by way of enteral feeding qualify as “medicines.” Staff believes the Board’s interpretation is specific to enteral feeding, TPN, and IDPN, and there is no statutory basis to extend the exemption to other medical appliances, instruments, or supplies. In addition, the inclusion of bags, tubing, etc. was based on the Board’s conclusion that they were integral parts of the liquid nutrition itself. Therefore, the exemption more properly belongs in subdivision (e), Specific Tax Applications, rather than in subdivision (b)(5), Prosthetic Devices.

SECOND DISCUSSION PAPER

Proposed Regulatory Changes to Clarify the Definition of “Worn on the Body” Regulation 1591, *Medicines and Medical Devices*

VI. Summary

Staff proposes to revise the regulation to include surgical clinics in the definition of “health facilities,” to move the reference to items used to dispense enteral feeding to new subdivision (e)(9), to make non-substantive corrections in subdivisions (c)(1) and (e)(7), and to incorporate the Board’s published decision regarding exempt sales of CPM machines. However, staff recommends that no other changes be made to the Board’s long-standing interpretation of the “designed to be worn on the body” requirement for orthotic and prosthetic devices. Interested parties propose to revise the regulation to replace staff’s fully worn on the body test with a test based on the predominant value of the part that is worn on the body, and to exempt the sales of all wound dressings.

Prepared by the Program Planning Division, Sales and Use Tax Department
Current as of May 15, 2002

G:\BTC\BTC TOPICS 2002\02-07 Reg 1591 - Worn on the Body\Working Files\1591 SDP.doc

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

References: Sections 6006 and 6369 Revenue and Taxation Code.

(a) DEFINITIONS.

(1) ADMINISTER. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. “Furnish” means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. “Health Facility” as used herein has the meaning ascribed to the term in sections 1200 and 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer ...”

(5) PHARMACIST. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) PHARMACY. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

- (A) The name or names and address of the patient or patients.
- (B) The name and quantity of the drug or device prescribed and the directions for use.
- (C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. “Medicines” means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) “MEDICINES.” The term “medicines” means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

“Preparations and similar substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. “Preparations and similar substances” also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) **PERMANENTLY IMPLANTED ARTICLES.** Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.

(3) **ARTIFICIAL LIMBS AND EYES.** Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) **ORTHOTIC DEVICES.** Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and

garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

- (A) Any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;
- (B) Any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or
- (C) Any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). ~~For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.~~

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous

nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) **DRUG INFUSION DEVICES.** Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.”

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(56)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX – IN GENERAL.

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) Prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) ~~F~~furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) ~~F~~furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) ~~S~~old to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) ~~S~~old to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) ~~E~~ffective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) **PRESCRIPTIONS.** No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) **LICENSED PHYSICIAN, DENTIST OR PODIATRIST.** Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patients for the medicines furnished.

(3) **HEALTH FACILITY.** Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) **PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR.** Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher

education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) **ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL.** Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) **VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS.** In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) **DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT.** Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment. They are not administered in the living body (“in vivo”). As the

substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(45), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(8) CPM MACHINES. Tax does not apply to sales or leases of continuous passive motion machines, whether they are fully worn or are functionally equivalent to those fully worn on the body of the user.

(9) ENTERAL FEEDING, TPN, IDPN DEVICES. Tax does not apply to the sales of bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. Tax does not apply to sales of needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

(f) INSURANCE PAYMENTS

(1) **MEDICAL INSURANCE AND MEDICAL.** The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) **Medicare Part A.** Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) **Medicare Part B.** Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) **EMPLOYER MEDICAL CONTRACTS.** Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser
Name of doctor
Date of sale
Item sold
The sale price

(2) **"DOUBLE DEDUCTION" UNAUTHORIZED.** The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

E&Y'S PROPOSAL**Regulation 1591. MEDICINES AND MEDICAL DEVICES.**

(b) "MEDICINES." The term "medicines" means and includes the following items:

(4) **ORTHOTIC DEVICES.** Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, then the device is not a medicine for the purposes of this regulation unless the price paid for the device is predominantly for the part that is worn. If the price paid for the device is predominantly for the part that is not worn, then only the price attributable to the part that is worn may be excluded from tax.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the-patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Unless the price paid for the device is predominantly for the part that is worn, Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency. If the price paid for the device is predominantly for the part that is not worn, then only the price attributable to the part that is worn may be excluded from tax.

Prosthetic devices that do not qualify as medicines include auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

BEFORE THE BOARD OF EQUALIZATION
OF THE STATE OF CALIFORNIA

In the Matter of the Late Protest
Under the Sales and Use Tax Law of:

Action Medical Products, Inc.
Account: SR FH 97-309543
Case ID: 57424

Appearances:

For Petitioner: Jacqueline Reynolds, President

For Sales and Use Tax Department: David Levine, Tax Counsel IV

For Appeals Section: John Abbott, Tax Counsel IV

MEMORANDUM OPINION

This opinion considers the merits of a late protest for the period May 10, 1991, through December 31, 1998. At the Board hearing, taxpayer protested a determination measured by \$865,982 for leases of certain types of continuous passive motion machines, leased in the same form as acquired and purchased ex-tax from out-of-state vendors. A physician must order the use of these machines. Patients use the machines for the treatment of injuries and, post-operatively, to deter stiffness and loss of range of motion in joints such as knees and hips. The affected limbs of these patients are strapped into the machines. Powered by electricity, the machines move the affected joints through a controlled range of motion. The taxpayer contended that these continuous passive motion machines qualify as medicines, specifically, orthotic devices exempt under Revenue and Taxation Code section 6369, subdivision (c)(3)(A). If so, the leases are exempt from tax.

The Sales and Use Tax Department contended that, while the machines met all other requirements of a medicine as defined in California Code of Regulations, title 18, section 1591, the machines were orthotic devices that patients did not fully wear on their bodies. Instead, the machines' support stands rested on the floor. The Department contended that it has long been Board policy that, in order to qualify as a medicine, orthotic devices must be fully worn on the body. By amendments to subdivision (b)(4) of section 1591, effective March 10, 2000 and applicable retroactively, the Board clarified that "If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation." However, the Department allowed the medicine exemption for taxpayer's leases of continuous passive motion machines that served the identical medical rehabilitation purpose for other joints, such as elbow and shoulder joints, but were fully worn on the body.

OPINION

Revenue and Taxation Code section 6369 provides in relevant part:

“(c)... ‘medicines,’ as used in this section means and includes any of the following:

¶...¶

(3)(A) Orthotic devices... designed to be worn on the person of the user as a brace, support, or correction for the body structure....”

Some continuous passive motion machines leased by the taxpayer were exempt, but others were classified as taxable, even though all the machines served the identical medical rehabilitation purpose. We conclude that the continuous passive motion machines at issue in this case qualify as orthotic devices pursuant to section 6369, subdivision (c)(3)(A), although they were not fully worn on the body. Grant the late protest with respect to the disputed transactions.

Adopted at Sacramento, California, on April 18, 2002.

Dean F. Andal_____, Member

Claude Parrish_____, Member

Marcy Jo Mandel*_____, Member

*For Dr. Kathleen Connell, pursuant to Government Code section 7.9.